

K062059

AIE

Advanced Image Enhancement, Inc.
Region of Interest Image Enhancement for Digital Mammography
Traditional 510(k) Submission

Section 5: 510(k) Summary

SEP - 6 2006

Submitter: Advanced Image Enhancement
306 Valentine Street
Fall River, MA 02720

Contact Person: Jillian M. Reed
Consultant
Reed Technical Associates, LLC

Date Prepared: July 19, 2006

Classification Name: Picture Archiving and Communications System

Proprietary Name: Advance Image Enhancement, Inc.'s Region of Interest Image Enhancement Software

Predicate Devices: Hologic, Inc.'s SecureView DX Softcopy Workstation (#K041555)

Device Description:

The Region of Interest Image Enhancement for Digital Mammography (ROIIE-DM) software created by Advanced Image Enhancement, Inc. is intended to improve the overall ability of an image reader to resolve abnormalities with greater confidence in their findings. The AIE software is intended to improve the sharpness and clarity of subtle image features. The device used with FDA cleared monitors may be used by a trained physician for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images for screening and diagnostic mammography, as well as any other DICOM multi-modality image. The intended operational environment is the radiology reading room or any other FDA approved environment.

Intended Use:

The Advance Image Enhancement, Inc.'s Region of Interest Image Enhancement software is intended to improve the sharpness and clarity of subtle image features. The device used with FDA cleared monitors may be used by a trained physician or healthcare professional for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images for screening and diagnostic mammography, as well as any other DICOM multi-modality image.

The AIE software is intended as an added tool residing on any DICOM image workstation for improving the radiologist's perception of image features on any lossless compressed or non-compressed multi-modality DICOM "for-presentation" image. This software would be used while the radiologist is reviewing magnification window image segments on FDA cleared monitors and is intended to complement existing DICOM image workstation functionality.

Warning: Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

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Substantial Equivalence:

Testing performed has shown that Advanced Image Enhancement, Inc.'s Region of Interest Image Enhancement Software is substantially equivalent to the Hologic, Inc.'s SecureView DX Softcopy Workstation for its intended use.

Discussion of Non-Clinical Testing Performed:

Thorough system verification and validation testing was performed to ensure the safe and effective use of the AIE Region of Interest Enhancement Software.

Discussion of Clinical Testing Performed:

A reader study, comprised of 6 MQSA certified Radiologists, was conducted where they performed a features analysis comparing the AIE Region of Interest Enhancement Software to the predicate device on 50 mammography cases.

Conclusions:

The information provided in this premarket notification submission has shown that the AIE Region of Interest Image Enhancement Software is substantially equivalent to the predicate device and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 6 2006

Advanced Image Enhancement, Inc.
c/o Ms. Jillian Reed
Regulatory and Clinical Affairs Consultant
Reed Technical Associates, LLC
25 Walnut Street
MONROE CT 06468

Re: K062059

Trade/Device Name: Advance Image Enhancement, Inc.'s Region of Interest Image Enhancement Software

Regulation Number: 21 CFR §892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: July 19, 2006

Received: July 20, 2006

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062059

Device Name: Advance Image Enhancement, Inc.'s Region of Interest Image Enhancement Software

Indications for Use:

The Advance Image Enhancement, Inc.'s Region of Interest Image Enhancement software is intended to improve the sharpness and clarity of subtle image features. The device used with FDA cleared monitors may be used by a trained physician or healthcare professional for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images for screening and diagnostic mammography, as well as any other DICOM multi-modality image.

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Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062059

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